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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,460	10/08/2003	Kenneth E. Kadziauskas	27564	1644

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EXAMINER	
HAND, MELANIE JO	

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3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/682,460	**Applicant(s)** KADZIAUSKAS ET AL.
	Examiner Melanie J. Hand	**Art Unit** 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *6,8,12,13,19,21,25-28,34,36 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-11,14-18,20,22-24,29-33,35,37-39,41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

Applicant's arguments, see Remarks, filed August 28, 2007, with respect to the rejection(s) of claim(s) 1-5,7,9-11, 14-18, 20, 22-24, 29-33, 35, 37-39, 41 and 42 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814).

With respect to **claim 1:** Urich teaches an infusion source for a ocular surgery having a needle in the form of infusion sleeve 14 having sharp tip 12 mounted coaxially therein with at least an irrigation lumen defined by the inner wall of sleeve 14 comprising: a fluid supply in the form of gravity bottle 18 (Col. 2, lines 14-23); an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen defined by sleeve 14 (Col. 4, lines 21-23). A tubular member in the form of surge suppresser 24 is disposed along an aspiration line 20, as part of and in fluid communication with said aspiration line 20 in that it is located inside of line 20, and an aspiration lumen in the form of an inner channel (not shown) within tip 12. The tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as "configured to" is interpreted as meaning "capable of". That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. ('448, Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. ('814, ¶0053)

With respect to **claim 2:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. ('448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 3:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. ('448, Fig. 1)

With respect to **claim 4:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, and is thus elastic. ('448, Col. 2, lines 41-44)

With respect to **claim 14:** Urich teaches an infusion source comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Urich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The handpiece 11 has a needle in the form of sleeve 14 with sharp tip 12 positioned therein at an end of said sleeve 14 with an irrigation lumen defined by the inner wall of sleeve 14 (Col. 2, lines 14-23); a fluid supply in the form of gravity bottle 18 (Col. 2, lines 23-25); an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen 14 (Col. 2, lines 23-27); and a tubular member in the form of surge suppresser 24 disposed along said aspiration line 20 and in fluid communication with an aspiration line 20 and an aspiration lumen in the form of an inner channel (not shown) within tip 12. Tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as "configured to" is interpreted as meaning "capable of". That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. ('814, ¶0053)

With respect to **claim 15:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. ('448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 16:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. ('448, Fig. 1)

With respect to **claim 17:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, which is an elastic material. ('448, Col. 2, lines 41-44)

Claims 5, 7, 9-11, 18, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814) as applied to claims 1-4 and 14-17 above, and further in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 5:** The combined teaching of Urich and Dillon does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, "phaco") needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheather from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich. ('009, Col. 5, lines 48-57, col. 6, lines 1-5)

With respect to **claim 7:** The sheath of the combined teaching of Urich and Dillon and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 5.

With respect to **claim 9:** With regard to the limitation "the sheath and expandable wall of the device of Urich and Dillon and Mackool are integrally molded", the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 10:** The device of Urich and Dillon and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation "molded in a spaced apart relation", such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 11:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching fo Urich and Dillon and Mackool fairly suggest an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 5.

With respect to **claim 18:** The combined teaching of Urich and Dillon does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, "phaco") needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheather from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and

Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich.

With respect to **claim 20:** The sheath of the combined teaching of Urich and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 18.

With respect to **claim 22:** With regard to the limitation "the sheath and expandable wall of the device of Urich and Dillon and Mackool are integrally molded", the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 23:** The device of Urich and Dillon and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation “molded in a spaced apart relation”, such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 24:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching of Urich and Dillon and Mackool fairly suggest an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 18.

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No.

2004/0229814) as applied to claims 1-4 and 14-17 above, and further in view of Sepielli (U.S. Patent No. 5,554,894).

With respect to **claim 29:** Urich teaches an ocular surgical system for performing ocular surgery on an eye, comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Urich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The system includes an irrigation lumen in the form of sleeve 14; a fluid supply 18; an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen 14; and a tubular member in the form of surge suppresser 24 disposed along said aspiration line 20 and in fluid communication with an aspiration line 20 and an aspiration lumen in the form of an inner channel (not shown) within tip 12. Tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as "configured to" is interpreted as meaning "capable of". That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. ('814, ¶0053)

Neither Urich nor Dillon teaches that the handpiece 11 is driven by a controller in the form of a control system having housing 103 through a power line. Sepielli teaches a footswitch 101 for controlling a surgical phacoemulsification handpiece for ophthalmic surgery that is connected to said handpiece via a power line in the form of cable 115 having connector 123. (Col. 4, lines 15-19) Sepielli teaches that the footswitch supplies power to the handpiece remotely and allows the surgeon to adjust the power settings or preset patterns remotely via switches 105,107,109,111 and a touch-screen display 133, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon such that handpiece 11 is driven by a controller through a power line as taught by Sepielli to provide a means for remotely powering and controlling the handpiece to prevent unnecessary interruption of surgery for adjustment. ('894, Col. 3, lines 28-38)

With respect to **claim 30:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. ('448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 31:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. ('448, Fig. 1)

With respect to **claim 32:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, which is an elastic material. ('448, Col. 2, lines 41-44)

Claims 33, 35 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814) and further in view of Sepielli (U.S. Patent No. 5,554,894) as applied to claims 29-32 above, and further in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 33:** The combined teaching of Urich and Dillon and Sepielli does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, "phaco") needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheather from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Sepielli such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and Sepielli and Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich. ('009, Col. 5, lines 48-57, col. 6, lines 1-5)

With respect to **claim 35:** The sheath of the combined teaching of Urich and Dillon and Sepielli and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Sepielli and Mackool is stated *supra* with respect to claim 33.

With respect to **claim 37:** With regard to the limitation "the sheath and expandable wall are integrally molded", the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable over the prior art of Urich and Dillon and Sepielli and Mackool even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 38:** The device of Urich and Dillon and Sepielli and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation "molded in a spaced apart relation", such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 39:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Sepielli and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching of Urich and Dillon and Sepielli and Mackool fairly suggests an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Sepielli and Mackool is stated *supra* with respect to claim 33.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 41:** Urich teaches an accumulator in the form of surge suppressor 24 defining an accumulator chamber 28 for an ocular surgical handpiece 11, comprising: a tubular portion 24 comprising an expandable elastic wall 26 inasmuch as the wall is made from an elastomeric material which imparts elastic capability. The accumulator 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid and enhanced flow of fluid into an aspiration lumen upon clearing of the occlusion, inasmuch as "configured to" is interpreted as meaning "capable of". That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. ('448, Col. 2, lines 25-37)

Urich does not teach a sheath disposed around the expandable elastic wall. Mackool teaches a phacoemulsification (hereafter, "phaco") needle having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle. Mackool teaches that the inner sheath 108 prevents the outer silicone sheather from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12.

With respect to **claim 42:** With regard to the limitation "the sheath and expandable wall of the device of Urich and Mackool are integrally molded", the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

October 15, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER